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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,811	10/28/2005	Luc Jugla	124185	5097

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EXAMINER
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PALENIK, JEFFREY T

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/537,811

Applicant(s)

JUGLA, LUC

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9 Jan. 2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 9-16 are presented and represent all of the claims under consideration.

### ***Priority***

This application is the National Stage filing of International Patent Application No. PCT/FR03/03900, filed 24 December 2004, and French Foreign Application 02/16723, filed 26 December 2002. Examiner finds that Applicant's filing meets the priority requirements for the International Application, but not the Foreign Application.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in France on 26 December 2002. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

As such it is determined that the earliest effective U.S. filing date to be 24 December 2004.

### ***Information Disclosure Statement***

An Information Disclosure Statements filed 09 January 2006 is acknowledged and has been reviewed.

### *Specification*

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. **It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Specifically, the phrase "and emulsion obtained" at the end of the title is not clear.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "raised to a temperature above the phase inversion temperature" lacks clarity. The former temperature requirement depends from the latter. Since the phase inversion temperature is not defined, it is not clear to which temperature the emulsion or emulsion phases are to be heated.

The term "liposoluble phase" in claim 9 is a relative term which renders the claim indefinite. The term " liposoluble phase " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As a result, the limitation of "fatty phase" in claim 9, is rendered indefinite as its degree of differentiation from the term "liposoluble phase" is not clear.

The term "effective" in claim 9 is a relative term which renders the claim indefinite. The term " effective " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The degree of completion of the phase inversion of the emulsion is rendered indefinite by the term "effective" in step (f) of claim 9.

Claim 10 recites the limitation "step c') in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

The term "some" in claim 12, is a relative term which renders the claim indefinite. The term "some" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The closest the claim or specification comes to elaborating on the term "some" is in the Examples' instructions for concentrating the emulsion via tangential ultracentrifugation. Despite further specifying a means to remove "some" of the aqueous phase, the degree to which this performed is not.

The recitation of "an additional amount" in claim 13 lacks clarity. The amount of aqueous phase to be added to the system is indefinite. In claim 13 the "additional amount of aqueous phase" is further made indefinite by requiring that the aqueous phase be at any

temperature below the undefined phase inversion temperature. Since the temperature beneath the phase inversion temperature is not specified it is impossible to know the additional amount of aqueous phase to add.

Claim 14 also recites "an additional amount" in deference to the amount of fatty phase needed to dissolve the active principle prior to its incorporation into the emulsion. Said amount is indefinite because different active principles inherently exhibit different dissolution properties in the presence of different fatty phases.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Allard et al. (US Patent 5,756,110).

Claim 9 is drawn to a process to encapsulate a liposoluble active principle through preparation of an emulsion wherein the aqueous and fatty phases provided are first heated above the phase inversion temperature (PIT), then mixed together. The resulting emulsion is mixed with the liposoluble active principle, the emulsion temperature is lowered to the phase inversion temperature and then further annealed (i.e. cooled) below the PIT. Claim 11 further limits the method by reversing steps b) and c) in claim 9: rather than separately heating the fatty and aqueous phases prior to mixing them, the two phases are mixed together and then heated. Allard et al. teaches in claim 1 that the method comprises of emulsifying a fatty and aqueous phase at a

temperature above the PIT of the medium and then cooling the established emulsion to below the PIT. It is further taught that an inorganic nanopigment is encapsulated within the emulsion either during the initial emulsification and or after cooling below the PIT. Claims 7 and 8 further define the nanopigment particulates as metal oxides (i.e. iron oxide). The instant claim 14 further limits the method of claim 9 by presenting the active principle for incorporation in to the system (e.g. the emulsion) already dissolved in the fatty phase. Claim 15 further limits the active principle to include liposoluble vitamins, polyphenols and fragrance components. Allard et al. teaches that the fatty phase can contain one or more traditional lipophilic adjuvants such as those incorporated into sunscreen compositions (col. 4, lines 47-50). Cosmetic lipophilic adjuvants that are taught include vitamins and perfumes (col. 5, lines 1-10).

It should be noted that claim 16, despite citing dependence from claim 9 is deemed a product-by-process claim due to the limitation, "that may be obtained via a process as claimed in claim 9" and as such, determination of patentability is based on the product itself, not by the method in which it is made. If the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113). Claim 16 does not further limit the method itself, but instead claims emulsion-produced nanocapsules averaging less than 300 nanometers (nm) in size (i.e. diameter). Allard et al. teaches at claim 16 that at least 90% of the globules produced from the emulsion resulting from claim 1, have a particle size ranging from 100 nm to 500 nm.

Therefore each of the limitations is met by the reference.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (U.S. Patent 5,756,110).

Allard is taught above, but does not specifically teach the method to include: 1) incorporation of the active principle at a temperature immediately above the phase inversion temperature (claim 10), 2) concentration of the emulsion by withdrawal of some of the aqueous phase (claim 12), or 3) reduction of the emulsion temperature to the phase inversion temperature by adding an additional quantity of aqueous phase cooled to a temperature below the phase inversion temperature (claim 13). However, it is the Examiner's position that adjustment of the concentration of a formulation (i.e. an emulsion) by removal of aqueous material is well known in the art, as shown by Allard et al. which teaches that the aqueous phase of the sunscreen/cosmetic formulation may vary from 50-90% by weight, relative to the total



formulation (col. 5, lines 18-24). Furthermore, a case of *prima facie* obviousness is upheld, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). As to the method limitations cited in claims 10 and 13, the Examiner holds the position that there is no patentable distinction between Applicant’s methods and the methods of the prior art. The selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) Selection of any order of mixing ingredients is also held to be *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (see MPEP 2144.04 (IV)(C.))

Additionally, the purpose of Applicant’s claimed invention is to supply a process to package pharmaceutical and/or cosmetic active agents which comprises of encapsulation within a PIT emulsion. The same problem and concern is addressed by the Allard reference. Allard teaches the same method which comprises of encapsulation of metal oxides that are formulated into a sunscreen cosmetic formulation (claim 1). Therefore, absent any evidence to the contrary, Applicant’s claimed invention achieves the same goal as that of the prior art, with no unexpected results. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

No claims are allowed.


*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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